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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/694,701	10/23/00	RAMPAL	J 1956-045

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EXAMINER

TUNG, J

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 07/05/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/694,701

Applicant(s)
Rampal et al.

Examiner
Joyce Tung

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1656



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above, claim(s) 1-28 and 43-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-28, drawn to a method of making an assay article for use in biopolymer detection, classified in class 422, subclass 50/186.05
 - II. Claims 29-42, drawn to a method of detecting a target biopolymer, classified in class 435, subclass 7.1/6.
 - III. Claims 43-54, drawn to an assay particle and kit, classified in class 422, subclass 88/61.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).
3. Inventions III and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product claims 43-54 can be used in nucleic acid or protein

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purification, the method claims 29-42 can be used with other solid support detection, for example magnetic beads.

4. Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, invention I, claims 1-28 can be used to make affinity chromatography column, while the method claims 29-42 can be used to make the magnetic beads for biopolymer detection.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Mr. Arnold Grant on 6/20/2001 a provisional election was made with traverse to prosecute the invention of II, claims 29-42. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-28 and 43-54 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

8. The title of the invention is not descriptive because the old title is directed to immobilization of biopolymers to aminated substrates by direct adsorption, while the claim language is directed to a method of detecting a target biopolymer involving immobilization of biopolymers to aminated substrates by direct adsorption. A new title is required that is clearly indicative of the invention to which the claims are directed.

9. The disclosure is objected to because of the following informalities: the word “complimentary” might be misspelling (See pg. 12, line 2 of the specification).

Appropriate correction is required.

10. Claims 33-34 are objected to because of the following informalities: the word “complimentary” might be misspelling (See claims 33). Appropriate correction is required.

Drawings

11. The drawings fig.s 1-2 are approved.

Claim Objections

12. Claims 35-37 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative but claim 35 depends from claims 34 and 29. See MPEP § 608.01(n). Accordingly, the claims 35-37 have not been further treated on the merits.

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Claim Rejections - 35 U.S.C. § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 29-31 and 38-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention since instant invention claims a method of detecting a target biopolymer, the specification only describes that the biopolymer used is nucleic acid and polypeptide or protein in the detection method (See pg. 6, lines 17-32). However, the term “biopolymer” includes carbohydrates and fatty acid. There are no teachings in the specification for one of ordinary skill in the art to detect carbohydrates or fatty acid.

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 29-34 and 38-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- a. ✓ Claims 29-34 and 38-42 are vague and indefinite because of the language "a direct adsorption". it is unclear what is meant by the language "a direct adsorption".
- b. No Claim 32 is vague and indefinite because of the language "analogues thereof". It is unclear how the language is defined in the specification.

Claim Rejections - 35 U.S.C. § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 29-34, 38 and 41-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Matson et al. (5,981,185).

Matson et al. disclose a solid support based hybridization assay for the analysis of repeat and tandem oligonucleotide sequence DNA and RNA by hybridization to a reverse dot blot array (See the Abstract). The support is an aminated polypropylene (See the Abstract) (as recited in claims 29(a), 30-31, 38-39 and 41). Aminating steps are involved before contacting step (See column 10, lines 21-31) (as recited in claim 42). A predetermined set of oligonucleotides is attached to the surface of the solid support (See column 3, lines 39-49) (as recited in claim 29(c)).

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The sequence forming the array may be directly linked to the support (See column 3, lines 60-61) (as recited in claim 29(c)). It is presently considered to synthesize the sequence directly onto the support to provide the desired array (See column 7, lines 9-11). The DNA and RNA samples are labeled in which the labeled target is the same manner as a labeled probe (See column 8, lines 28-32) (as recited in claim 33). The labeling is fluorescence or chemiluminescence (See the Abstract and column 8, lines 44-46) (as recited in claim 34). Oligonucleotides were synthesized directly to the aminated polypropylene substrate to prepare the discrete oligonucleotide sequence in parallel rows across the polypropylene substrate (See column 10, lines 21-31) (as recited in claim 38).

Matson et al. do not disclose that the solid support is used for detecting biopolymer, however, the tandem repeat oligonucleotide is one type of biopolymer which is known in the art at the time of instant invention.

The teachings of Matson et al. anticipate the limitations of instant claims 29-34, 38 and 41-42. Instant claims 29-34, 38 and 41-42 are drawn to a method of detecting a target biopolymer. The method involves contacting either probe or target biopolymer with a surface of the substrate, contacting the probe assay article to the target or contacting the target to the probe to form a complex comprising the probe and the target and detecting the presence of the complex for determining the presence of the target. The substrate is the amino-modified polypropylene. The target is nucleic acid or protein and the probe is nucleic acid or protein. The complex comprises a reporter selected from the group consisting of dyes, chemiluminescent compounds, fluorescent compounds as listed in claim 34. The probe or target is adsorbed on discrete, isolated

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areas on the surface of the aminated polypropylene substrate to form an array. Thus the teachings of Matson et al. anticipate the limitations of claims 29-34, 38 and 41-42.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

19. Claims 29-34 and 38-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Rampal (6,013,789).

Rampal discloses a method for attaching pre-synthesized oligonucleotides to a polypropylene support medium which is aminated (as recited in claims 29-31 and 41-42) and that the invention is used to construct oligonucleotide arrays for hybridization assays (See the Abstract) (as recited claim 29 and 32-33). The covalently attached oligonucleotides can then serve as probes for target DNA (See column 3, lines 28-29) and used in genetic analysis for the purpose of medical and diagnostic evaluation (See column 3, lines 63-66). This is inherent that the array is for detecting biopolymer as claimed. The polypropylene support is used for fluorescence detection procedures (See column 4, lines 5-9). A labeled detection oligonucleotide is complementary to the target and the labels act as reporter groups for detecting complex formation (See column 9, lines 11-19) (as recited in claim 29). The labeling would be the biotinylation of a target or the detection oligonucleotide in which the biotin moieties bind to an avidin-enzyme conjugate (See column 9, lines 20-26) (as recited in claim 34). The label can also be fluorescent compounds (See column 9, lines 26-28) (as recited in claim 34). To detect

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biotinylated oligo target, the enzyme substrate, ELF, was used and the signals were detected by a CCD camera (See column 11, lines 13-27) (as recited in claims 39-40).

Rampal doesn't disclose that the probe or target is adsorbed on discrete, isolated areas on the surface of the aminated polypropylene substrate to form an array, but the method is inherent that because if the probe or target is adsorbed on overlapped areas on the surface of the aminated polypropylene substrate to form an array, the array will not be properly working and can not be used in genetic analysis for the purpose of medical and diagnostic evaluation (See column 3, lines 63-66).

The teachings of Rampal anticipate the limitations of instant claims 29-34, 38-42. Instant claims 29-34 and 38-42 are drawn to a method of detecting a target biopolymer. The method involves contacting either probe or target biopolymer with a surface of the substrate, contacting the probe assay to the target or contacting the target to the probe to form a complex comprising the probe and the target and detecting the presence of the complex for determining the presence of the target. The substrate is the amino-modified polypropylene. The target is nucleic acid or protein and the probe is nucleic acid or protein. The complex comprises a reporter selected from the group consisting of dyes, chemiluminescent compounds, fluorescent compounds as listed in claim 34. The probe or target is adsorbed on discrete, isolated areas on the surface of the aminated polypropylene substrate to form an array. Biotin is used for the reporter. The detection signal is recorded by a CCD camera. Thus, the teachings of Rampal anticipate the limitations of claims 29-34 and 38-42.

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20. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at (703) 308-1152.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

21. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

June 26, 2001 